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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Cerami et al.

Application No.: 09/259,929

Group Art Unit: 1615

Filed: March 1, 1999

Examiner: Webman, Edward J.

For: METHODS AND DEVICES FOR MODULATING
THE IMMUNE RESPONSE

Attorney Docket No.: 10162-004-999

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RESPONSE TO RESTRICTION REQUIREMENT UNDER 37 C.F.R. § 1.143Assistant Commissioner for Patents
Washington, D.C. 20231

Sir or Madam:

In response to the Office Action dated June 12, 2000, and pursuant to Rule 143 of the Rules of Practice, please consider the remarks below. Applicants submit herewith a Petition for Extension of Time for a period of one month.

REMARKS

According to the Office Action mailed June 14, 2000, Claims 1-57 are pending in the instant application. A copy of the pending claims is attached hereto as Exhibit B.

The Examiner has required restriction to one of the following inventions:

- I. Claims 1-19, 32-37, and 47-57, drawn to a method of using, classified in class 935, subclass 1+; and
- II. Claims 20-31 and 38-46, drawn a product, classified in class 424, subclass 425.

Applicants respectfully traverse the Examiner's restriction requirement. Specifically, Applicants request a modification of the requirement so that Groups I (Claims 1-19, 32-37, and 47-57) and II (20-31 and 38-46) be combined. Thus, Applicants request that Claims 1-57 be examined together in the instant application.

The Examiner contends that the inventions of Groups I and II are distinct from each other. In particular, the Examiner contends that, the product and process of using the product are distinct inventions, because, pursuant to MPEP § 806.05(h), the product can be used in a materially different process of using that product. As an example, the Examiner states that the process can be

used with cultured cells. Applicants respectfully disagree. Contrary to the Examiner's contention, using the device in cell culture would not necessarily constitute a "materially different" process of using the device. For example, the device could be used in cell cultures to expose immune cells to antigen, or other molecule, within the porous matrix of the device, for the purpose of obtaining, stimulating, or transfecting immune cells, or producing hybridomas. Such processes are exactly analogous to the processes of using the device when the device is implanted in a mammal. Thus, since the device is used in a similar manner to perform the same function, whether *in vivo* or *ex vivo*, the Examiner has not identified a materially different process of using the device.

Even assuming, *arguendo*, that Groups I and II were to represent distinct inventions, Applicants assert that, pursuant to MPEP § 803, examination of Groups I and II together would not constitute an undue burden to the Examiner. Applicants submit that only a single search and examination would be required to search and examine the subject matter of Groups I and II. A search of the relevant art pertinent to a method for using the implantable device of the invention will necessarily reveal any relevant art pertaining to the device itself. Thus, a search of the prior art for the implantable device of Group II (Claims 20-31 and 38-46) is commensurate in scope with a search of the prior art for methods which utilize said implantable device. Therefore, Applicants request that Groups I and II be combined and examined together.

Despite Applicants' traversal, in order to be completely responsive to the outstanding restriction requirement, Applicants hereby provisionally elect Group I, claims 1-19, 32-37, and 47-57, drawn to a method of using an implantable device. The Examiner has further requested that a single species be elected for prosecution on the merits to which the claims shall be restricted if no generic claim is held to be allowable. In response, Applicants elect Claims 1-19, 48-50, and 55-57, directed to a method for modulating an immune response.

Entry of the foregoing remarks is respectfully requested. Applicants do not believe there is a fee due in connection with this response. However, should the Patent and Trademark Office determine otherwise, please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

by Eileen Fahcy

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Date August 14, 2000

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Enclosure